#### FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 678115245 US

Feb. 9,2506

Express Mail Label Number

Date of Deposit

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ROHRA ET AL.

**APPLICATION NO: 10/540,448** 

FILED: September 1, 2005

FOR: SLOW RELEASE FORMULATION OF CLARITHROMYCIN

MS PCT

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

#### LETTER CORRECTING OFFICIAL FILING RECEIPT

Sir:

The official filing receipt received in the above-identified application erroneously lists the "Foreign Applications". Enclosed is a copy of the title page of the International Publication No. WO2004/056344. Please issue a corrected filing receipt listing the foreign application area as follows:

-- Foreign Applications UNITED KINGDOM 0230034.1 12/23/2002 .--

A copy of the filing receipt with the correction noted is enclosed.

No fee is believed to be required by this request for a corrected filing receipt.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(609) 627-8507
JDT:nb
Ensistence of filing receipt

Encl: copy of filing receipt copy of WO2004/056344

Date: February 8, 2006

John D. Thallemer Attorney for Applicants Reg. No. 34,940



### JNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P. Dox 1450 Alexandria, Virginia 22313-1450

FILING OR 371 APPL NO. **ART UNIT** FIL FEE REC'D ATTY.DOCKET NO DRAWINGS TOT CLMS IND CLMS (c) DATE 10/540,448 10 2

JAN 2006

RECEIVED

Linda C. Rothwell **Patent** 

18086281

09/01/2005

1615

1030

RG/G-32840A

**CONFIRMATION NO. 1580** 

FILING RECEIPT

\*OC000000017354943\*

Date Mailed: 01/09/2006

1095 **NOVARTIS** CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 **EAST HANOVER, NJ 07936-1080** 

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

#### Applicant(s)

Rakhi H. Rohra, Maharashtra, INDIA; Mallika Tushakiran, Mumbai, INDIA; Chetan Doshi, Mumbai, INDIA; Virendra M. Khanapure, Thane, INDIA; Dinesh C. Nambiar, Mumbai, INDIA; Erich Zeisl, Wiesing, AUSTRIA;

Power of Attorney: The patent practitioners associated with Customer Number 1095.

# Domestic Priority data as claimed by applicant

This application is a 371 of PCT/EP03/14755 12/22/2003

# Foreign Applications

UNITED KINGDOM 02300034.1 12/23/2002

ではいてるかし

Projected Publication Date: To Be Determined - pending completion of Security Review

Non-Publication Request: No

Early Publication Request: No

Title

Slow release formulation of clarithromycin

**Preliminary Class** 

514

# PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but does not result in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filling receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

# LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

#### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

# (19) World Intellectual Property Organization International Bureau





(43) International Publication Date 8 July 2004 (08.07.2004)

PCT

# (10) International Publication Number WO 2004/056344 A1

(51) International Patent Classification<sup>7</sup>: 31/7048

A61K 9/22,

(21) International Application Number:

PCT/EP2003/014755

(22) International Filing Date:

22 December 2003 (22.12.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

0230034.1

23 December 2002 (23.12.2002) GI

(71) Applicant (for all designated States except US): SANDOZ GMBH [AT/AT]; Biochemiestrasse 10, A-6250 Kundl (AT).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ROHRA, Rakhi, H. [IN/IN]; 26/685, Yashodeep Co. Hou. Soc., Nehru Nagar, Kurla (East), Mumbai, 400024 Maharashtra (IN). TUSHAKIRAN, Mallika [IN/IN]; B-3 Sai Niketan, Sai Baba Complex, Ciba Road, Goregaon (East), Mumbai 400063, Maharashtra State (IN). DOSHI, Chetan [IN/IN]; C-3, 403, Veenasagar, Co-Operative Housing Society, Lal Bahadur Shashtri Marg, Mulung (West).

Mumbai 400 080 (IN). KHANAPURE, Virendra, M. [IN/IN]; A-1/301, IIyde Park Regency Co-Op Housing Society, B/H Greenwood Complex, Ghodbandar Road, Thane (west), 400607 (IN). NAMBIAR, Dinesh [IN/IN]; 203/13B- 1 Shantiniketan, Kanderpada, Dahisar West, Mumbai 400068 (IN). ZEISL, Erich [AT/AT]; Wiesing 74b, A-6200 Wiesing (AT).

- (74) Agent: GRUBB, Philip; Novartis AG, Corporate Intellectuel Property, CH-4002 Basel (CH).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LT, LU, LV, MA, MD, MK, MN, MX, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SE, SG, SK, SY, TJ, TM, TN, TR, TT, UA, US, UZ, VC, VN, YU, ZA, ZW.
- (84) Designated States (regional): Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

#### Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SLOW RELEASE FORMULATION OF CLARITHROMYCIN

(57) Abstract: The invention relates to an orally administrable pharmaceutical composition comprising an alginate matrix consisting of a water-soluble alginate salt and a complex salt of alginic acid, a macrolide, and an inorganic salt characterized in that the inorganic salt is capable of donating a proton and has a pK<sub>a</sub> value in water of 4.0 to 9.0.